

What is Claimed:

1. A bioimplantable device comprising at least one region or layer for intimate contact with body tissue, said intimal layer or region either comprising or being in fluid communication with a portion of the device comprising a polyetherurethane;

the polyetherurethane being modified by admixture with a siloxane surface modifying additive;

at least some of the modified polyetherurethane portion containing a therapeutic agent.

2. The device of claim 1 wherein fewer than all polyetherurethane portions of the device contain therapeutic agent.

3. The device of claim 1 wherein all polyetherurethane portions contain therapeutic agent.

4. The device of claim 1 wherein the therapeutic agent is loaded on at least some but not all of the siloxane modified polyetherurethane portion of a region or layer.

5. The device of claim 1 wherein the therapeutic agent is loaded on all of the siloxane modified polyetherurethane portion of a region or layer.

6. The device of claim 1 adapted for service in an organ.

7. The device of claim 1 adapted for service in a tissue.

8. The device of claim 1 adapted for service as an anatomical support.

9. The device of claim 1 adapted for service as an arteriovenous shunt.

10. The device of claim 1 adapted for service as a stent.

11. The device of claim 1 adapted for service as a stent graft.

12. The device of claim 1 adapted for service as an endograft.

13. The device of claim 1 adapted for service as a vascular prosthesis.
14. The device of claim 1 adapted for service as a catheter.
15. The device of claim 1 wherein an agent soluble in siloxane modified polyetherurethane solution, is loaded in the range from about 0.001 to 40 weight percent of siloxane modified polyetherurethane.
16. The device of claim 1 wherein an agent soluble in siloxane modified polyetherurethane solution, is loaded in the range from about 0.001 to 30 weight percent of siloxane modified polyetherurethane.
17. The device of claim 1 wherein an agent soluble in siloxane modified polyetherurethane solution, is loaded in the range from about 0.001 to 20 weight percent of siloxane modified polyetherurethane.
18. The device of claim 1 wherein an agent soluble in siloxane modified polyetherurethane solution, is loaded in the range from about 0.001 to 10 weight percent of siloxane modified polyetherurethane.
19. The device of claim 1 wherein an agent soluble in siloxane modified polyetherurethane solution, is loaded in the range from about 0.001 to 5 weight percent of siloxane modified polyetherurethane.
20. The device of claim 1 wherein the loading is of an amount greater than about 10% of a systemically effective amount by weight of the composition.
21. The device of claim 1 wherein the loading is of an amount less than a systemically effective amount by weight of the composition.
22. The device of claim 1 wherein the loading is of an amount less than about 50% of a systemically effective amount by weight of the composition.
23. The device of claim 1 wherein the loading is of an amount less than about 40% of a systemically effective amount by weight of the composition.

24. The device of claim 1 wherein the loading is of an amount less than about 30% of a systemically effective amount by weight of the composition.
25. The device of claim 1 wherein the loading is of an amount less than about 20% of a systemically effective amount by weight of the composition.
26. The device of claim 1 wherein the loading is of an amount less than about 10% of a systemically effective amount by weight of the composition.
27. The device of claim 1 wherein the loading is of an amount greater than zero but less than about 5% of a systemically effective amount by weight of the composition.
28. The device of claim 1 wherein the loading is determined based on the loading of a layer.
29. The device of claim 1 wherein the loading is determined based on the loading of at least one, but fewer than all, layers.
30. The device of claim 1 wherein the loading is determined based on the loading of all layers.
31. The device of claim 1 wherein the polyetherurethane polymer of at least one layer comprises at least about 1 percent by weight of a polysiloxane-polyurethane copolymer surface modifying agent.
32. The device of claim 1 wherein the polyetherurethane polymer of at least one layer comprises at least from about 1 to about 5 percent by weight of a polysiloxane polyurethane copolymer surface modifying agent.
33. The device of claim 1 wherein the polyetherurethane polymer of at least one layer comprises from about 1 to about 40 percent by weight of a polysiloxane polyurethane copolymer surface modifying agent.
34. The device of claim 1 wherein said therapeutic agent is rapamycin.
35. The device of claim 1 wherein said therapeutic agent is paclitaxel.
36. The device of claim 1 wherein a plurality of therapeutic agents is loaded onto the device.

37. The device of claim 36 wherein the plurality of therapeutic agents are loaded onto different layers of the device.

38. The device of claim 36 wherein the plurality of therapeutic agents do not contact one another.

39. The device of claim 36 wherein the plurality of therapeutic agents are loaded onto the same layer of the device.

40. The device of claim 39 wherein at least two of the plurality of therapeutic agents do not physically contact one another.

41. A method of preventing or inhibiting development of hyperplasia comprising contacting a mammal with the prosthetic device of claim 1.

42. A method of localized delivery of a therapeutic agent to a target location within a mammal, comprising contacting a vessel within said mammal with the prosthetic device of claim 1.

43. A vascular graft comprising a generally tubular polyetherurethane and having two ends, said graft comprising:

an intimal layer comprising a substantially microporous polyetherurethane;

an intermediate layer comprising a substantially nonporous polyetherurethane; and

an adventitial layer comprising a substantially microporous polyetherurethane;

wherein the polyetherurethane of said layers may be the same or different; and

the polyetherurethane of at least one layer being modified by admixture with a siloxane surface modifying additive and

at least a portion of the polyetherurethane modified by admixture with siloxane containing polymer of at least one layer contains at least one therapeutic agent.

44. The graft of claim 43 wherein said therapeutic agent is loaded along the length of the graft.
45. The graft of claim 43 wherein the therapeutic agent is loaded at at least one end of the graft.
46. The graft of claim 43 adapted for service as an arteriovenous shunt.
47. The graft of claim 43 adapted for service as a stent.
48. The graft of claim 43 adapted for service as a stent graft.
49. The graft of claim 43 adapted for service as an endograft.
50. The graft of claim 43 adapted for service as a vascular prosthesis.
51. The graft of claim 43 adapted for service as an anatomical support.
52. The graft of claim 43 adapted for service as a catheter.
53. The graft of claim 43 wherein the therapeutic agent is loaded at the venous end of said graft while the arterial end is substantially free of therapeutic agent.
54. The graft of claim 43 wherein substantially all of said loading resides within about 10 cm from said venous end.
55. The graft of claim 43 wherein substantially all of said loading resides within about 5 cm from said venous end.
56. The graft of claim 43 wherein said therapeutic agent is loaded on the intimal and intermediate layer.
57. The graft of claim 56 wherein said therapeutic agent is loaded on the venous end of the graft while the arterial end is substantially free of said therapeutic agent.

58. The graft of claim 56 wherein said therapeutic agent is also loaded on said adventitial layer.
59. The graft of claim 43 wherein said therapeutic agent is loaded on the venous end of each of the three layers while the arterial end is substantially free of said therapeutic agent.
60. The graft of claim 43 wherein from about 1 nanogram to about 5000 mg of therapeutic agent is loaded onto the graft.
61. The device of claim 43 wherein an agent soluble in siloxane modified polyetherurethane solution, is loaded in the range from about 0.001 to 40 weight percent of siloxane modified polyetherurethane.
62. The device of claim 43 wherein an agent soluble in siloxane modified polyetherurethane solution, is loaded in the range from about 0.001 to 30 weight percent of siloxane modified polyetherurethane.
63. The device of claim 43 wherein an agent soluble in siloxane modified polyetherurethane solution, is loaded in the range from about 0.001 to 20 weight percent of siloxane modified polyetherurethane.
64. The device of claim 43 wherein an agent soluble in siloxane modified polyetherurethane solution, is loaded in the range from about 0.001 to 10 weight percent of siloxane modified polyetherurethane.
65. The device of claim 43 wherein an agent soluble in siloxane modified polyetherurethane solution, is loaded in the range from about 0.001 to 5 weight percent of siloxane modified polyetherurethane.
66. The device of claim 43 wherein the loading is of an amount greater than about 10% of a systemically effective amount by weight of the composition.
67. The graft of claim 43 wherein the loading is of an amount less than a systemically effective amount by weight of the composition.

68. The graft of claim 43 wherein the loading is of an amount less than about 50% of a systemically effective amount by weight of the composition.
69. The graft of claim 43 wherein the loading is of an amount less than about 40% of a systemically effective amount by weight of the composition.
70. The graft of claim 43 wherein the loading is of an amount less than about 30% of a systemically effective amount by weight of the composition.
71. The graft of claim 43 wherein the loading is of an amount less than about 20% of a systemically effective amount by weight of the composition.
72. The graft of claim 43 wherein the loading is of an amount less than about 10% of a systemically effective amount by weight of the composition.
73. The graft of claim 43 wherein the loading is of an amount greater than zero but less than about 5% of a systemically effective amount by weight of the composition.
74. The graft of claim 43 wherein the polyetherurethane polymer of at least one layer comprises at least about 1 percent by weight of a polysiloxane-polyurethane copolymer surface modifying agent.
75. The graft of claim 43 wherein the polyetherurethane polymer of at least one layer comprises at least from about 1 to about 5 percent by weight of a polysiloxane polyurethane copolymer surface modifying agent.
76. The graft of claim 43 wherein the polyetherurethane polymer of at least one layer comprises from about 1 to about 40 percent by weight of a polysiloxane polyurethane copolymer surface modifying agent.
77. The graft of claim 43 wherein said therapeutic agent is rapamycin.
78. The graft of claim 43 wherein said therapeutic agent is paclitaxel.
79. The graft of claim 43 wherein a plurality of therapeutic agents is loaded onto the graft.

80. The graft of claim 79 wherein the plurality of therapeutic agents are loaded onto different layers of the graft.
81. The graft of claim 79 wherein the plurality of therapeutic agents do not contact one another.
82. The graft of claim 79 wherein the plurality of therapeutic agents are loaded onto the same layer of the graft.
83. The graft of claim 82 wherein at least two of the plurality of therapeutic agents do not physically contact one another.
84. A method of preventing or inhibiting development of hyperplasia comprising contacting a mammal with the prosthetic graft of claim 43.
85. A method of localized delivery of a therapeutic agent to a target location within a mammal, comprising contacting a vessel within said mammal with the prosthetic graft of claim 43.
86. The method of claim 85 wherein said target location is substantially the proximal or distal anastomosis.
87. The method of claim 85 wherein said target location is substantially the arterial or the venous anastomosis.
88. A method of forming a prosthetic graft containing polyetherurethane and a therapeutic agent comprising contacting a prosthetic graft containing a polyetherurethane with a solution comprising a solvent and said therapeutic agent for a period of time sufficient to load said graft with a desired amount of therapeutic agent, wherein the solvent substantially swells the polymer allowing the agent to diffuse into the polymer matrix while said polyetherurethane is substantially insoluble in said solvent.
89. A method for forming a prosthetic graft which includes a therapeutic agent comprising:
mixing said therapeutic agent with a polyetherurethane polymer solution;
manufacturing the device;

applying the polymer to the intimal and adventitial surfaces of a polyethylene terephthalate or polytetrafluoroethylene graft.

90. A method for forming a coating comprising polyetherurethane polymer with siloxane based surface additives, said polymer loaded with a therapeutic agent.

91. The coating of claim 90 applied to a medical device.

92. The coating of claim 90 comprising rapamycin as a therapeutic agent.

93. The coating of claim 90 comprising paclitaxel as a therapeutic agent.

94. A biocompatible device comprising a blend of polyetherurethane polymer with siloxane based surface modifying additive, said blend being loaded with at least one therapeutic agent.

95. A device comprising a polyetherurethane having one or more layers, at least part of one layer comprising an admixture of siloxane surface modifying additive, and at least part of a layer comprising one or more therapeutic agents.

96. The device of claim 95 wherein the layers are anisotropically distributed throughout the device.